§ 880.5440 Intravascular administration set.

(a) *Identification.* An intravascular administration set is a device used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein. The device may include the needle or catheter, tubing, a flow regulator, a drip chamber, an infusion line filter, an I.V. set stopcock, fluid delivery tubing, connectors between parts of the set, a side tube with a cap to serve as an injection site, and a hollow spike to penetrate and connect the tubing to an I.V. bag or other infusion fluid container.

(b) *Classification.* Class II (special controls). The special control for pharmacy compounding systems within this classification is the FDA guidance document entitled ''Class II Special Controls Guidance Document: Pharmacy Compounding Systems; Final Guidance for Industry and FDA Reviewers.'' Pharmacy compounding systems classified within the intravascular administration set are exempt from the premarket notification procedures in subpart E of this part and subject to the limitations in § 880.9.

[45 FR 69682, Oct. 21, 1980, as amended at 66 FR 15798, Mar. 21, 2001]

§ 880.5450 Patient care reverse isolation chamber.

(a) *Identification.* A patient care reverse isolation chamber is a device consisting of a roomlike enclosure designed to prevent the entry of harmful airborne material. This device protects a patient who is undergoing treatment for burns or is lacking a normal immunosuppressive defense due to therapy or congenital abnormality. The device includes fans and air filters which maintain an atmosphere of clean air at a pressure greater than the air pressure outside the enclosure.

(b) *Classification.* Class II (performance standards).

§ 880.5475 Jet lavage.

(a) *Identification.* A jet lavage is a device used to clean a wound by a pulsatile jet of sterile fluid. The device consists of the pulsing head, tubing to connect to a container of sterile fluid, and a means of propelling the fluid through the tubing, such as an electric roller pump.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9.

[45 FR 69682, Oct. 21, 1980, as amended at 63 FR 59229, Nov. 3, 1998]

§ 880.5500 AC-powered patient lift.

(a) *Identification.* An AC-powered lift is an electrically powered device either fixed or mobile, used to lift and transport patients in the horizontal or other required position from one place to another, as from a bed to a bath. The device includes straps and slings to support the patient.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9.

[45 FR 69682, Oct. 21, 1980, as amended at 63 FR 59229, Nov. 3, 1998]

§ 880.5510 Non-AC-powered patient lift.

(a) *Identification.* A non-AC-powered patient lift is a hydraulic, battery, or mechanically powered device, either fixed or mobile, used to lift and transport a patient in the horizontal or other required position from one place to another, as from a bed to a bath. The device includes straps and a sling to support the patient.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9.

[45 FR 69682, Oct. 21, 1980, as amended at 54 FR 25050, June 12, 1989; 66 FR 38804, July 25, 2001]

§ 880.5550 Alternating pressure air flotation mattress.

(a) *Identification.* An alternating pressure air flotation mattress is a device intended for medical purposes that consists of a mattress with multiple air cells that can be filled and emptied in an alternating pattern by an associated control unit to provide regular, frequent, and automatic changes in the

distribution of body pressure. The device is used to prevent and treat decubitus ulcers (bed sores).

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9.

[45 FR 69682, Oct. 21, 1980, as amended at 63 FR 59229, Nov. 3, 1998]

§ 880.5560 Temperature regulated water mattress.

(a) *Identification.* A temperature regulated water mattress is a device intended for medical purposes that consists of a mattress of suitable size, filled with water which can be heated or in some cases cooled. The device includes electrical heating and water circulating components, and an optional cooling component. The temperature control may be manual or automatic.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9.

[45 FR 69682, Oct. 21, 1980, as amended at 61 FR 1123, Jan. 16, 1996; 66 FR 38804, July 25, 2001]

§ 880.5570 Hypodermic single lumen needle.

(a) *Identification.* A hypodermic single lumen needle is a device intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin. The device consists of a metal tube that is sharpened at one end and at the other end joined to a female connector (hub) designed to mate with a male connector (nozzle) of a piston syringe or an intravascular administration set.

(b) *Classification.* Class II (performance standards).

§ 880.5580 Acupuncture needle.

(a) *Identification.* An acupuncture needle is a device intended to pierce the skin in the practice of acupuncture. The device consists of a solid, stainless steel needle. The device may have a handle attached to the needle to facilitate the delivery of acupuncture treatment.

(b) *Classification.* Class II (special controls). Acupuncture needles must comply with the following special controls:

(1) Labeling for single use only and conformance to the requirements for prescription devices set out in 21 CFR 801.109,

(2) Device material biocompatibility, and

(3) Device sterility.

[61 FR 64617, Dec. 6, 1996]

§ 880.5630 Nipple shield.

(a) *Identification.* A nipple shield is a device consisting of a cover used to protect the nipple of a nursing woman. This generic device does not include nursing pads intended solely to protect the clothing of a nursing woman from milk.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9.

[45 FR 69682, Oct. 21, 1980, as amended at 59 FR 63011, Dec. 7, 1994; 66 FR 33804, July 25, 2001]

§ 880.5640 Lamb feeding nipple.

(a) *Identification.* A lamb feeding nipple is a device intended for use as a feeding nipple for infants with oral or facial abnormalities.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[45 FR 69682, Oct. 21, 1980, as amended at 66 FR 38804, July 25, 2001]

§ 880.5680 Pediatric position holder.

(a) *Identification.* A pediatric position holder is a device used to hold an infant or a child in a desired position for therapeutic or diagnostic purposes, e.g., in a crib under a radiant warmer, or to restrain a child while an